RESOLVE
Establishment of Electronic Reporting; Electronic Records
Informal Public Hearing
Chicago, Illinois
November 9, 2001

[*To improve the succinctness of these transcripts, the facilitator's comments have been minimized or deleted. Comments by hearing participants that were inaudible or not specifically about the subject matter have also been deleted. Minor edits have been made to improve readability. Raw transcripts are available from RESOLVE upon request.*]

Robin Roberts: I'm not an employee of EPA, nor do I advocate for any of their policies. I'm just here to be sure that we stay on track in terms of time and topic area indicated on the agenda.

The purpose of this informal public hearing is to provide you, the interested public, with an opportunity to supplement your written formal comments to EPA with oral comments and to seek clarification where needed on a proposed rule. The proposed electronic reporting and records rule was published on August 31. The formal public comment period ends November 29 and written comments must be submitted to the docket at that time. Instructions for submitting your comments to the docket are included on the notice of the rule. There's a copy

at the front desk if you'd like to see what those instructions are. This informal hearing is not intended in lieu of submitting formal written comments. Nonetheless this hearing is being recorded and a transcript will be provided to the docket.

I'd just like to turn to the panel and introduce them at this time. We have Joe Retzer, Director, Collections Services Division, Office of Environmental Information (OEI); David Schwarz, the co-chair of the Electronic Reporting and Record-keeping Work Group, also with OEI; and Michael Le Desma, Office of General Counsel's liaison to OEI. What I'll do if you'll just pull out your agendas, you'll see that we're going to start with an overview of the rule…

David Schwarz: Okay, well. Good morning. I'd like to, first of all, thank you all for coming out. I know that some of you have traveled a ways to be with us, and I know that in today's environment that takes a certain amount of effort and expense. And I wanted to thank you for coming to share your thoughts with us.

Subpart A - General Provisions:

What I'd like to do is to take about 20 minutes and give

you a little background and kind of an overview of the rule, and then I'll sort of take a breath. And then I'll launch into the first section, which is electronic reporting to EPA. One thing I'd add to what Robin has said is that we'll also take questions and try to answer them to the best of our ability, so if you have questions as well as comments, please feel free to ask them.

So we're going to talk a little bit about what reporting is like in general under EPA rules, what our electronic government goals and strategy are, and then a little bit about the rule in general, its scope, the approach, the interest affected, and the general provisions. And that will be the place where I'll kind of take my breath. And then we'll launch into the electronic reporting to EPA. So why don't we move into the background.

This is a general point. We don't need to dwell on it too much, but why are we interested in electronic reporting, electronic recordkeeping. Well, obviously it makes sense. We hope it will save us money, time, and improve the quality of the product. Something that you may not know is that there is also a federal mandate in something called the Government Paperwork Elimination Act of 1998, which mandates federal agencies to offer options for electronic reporting and record-

keeping by October 2003. So the timing of the rule of CROMERRR and our other efforts are really, in part, aimed at making sure that we can comply with that mandate and meet the deadline.

Reporting and record-keeping under EPA rules is a broad and complex body of activities. There are more than ten different statutory programs, as I'm sure most of you know, air water, waste, drinking water and so on. And there are many different kinds of reports. There are many different kinds of records. Record retention periods range from three to as much as 30 years and that creates certain problems and issues.

In addition, EPA is probably the first federal agency to address electronic government issues where programs are run in fact by state and local agencies through some kind of authorization. So there's that added layer of complexity of trying to address the relationship between our regulations and the state and local agencies that carry them out.

And another way of thinking about the reporting and record-keeping and thinking about the rule in the state and local governments, the overwhelming majority of reporting is actually done to state or local agencies. In total that's 97% of the reports coming in. EPA only collects sort of 3% of the

reports that we actually require, about 400,000 reports coming from about 90,000 facilities. So the state and local component is very important.

Moving on to our strategy, we are trying both with the rule and in our systems development to take an agency wide approach, rather than a program-by-program approach. We think that that will give both industry and the states and local governments that we deal with a consistent and predictable way for all of you to interact with us electronically.

We have a much better chance of accomplishing that if we take an agency-wide approach. And then of course, there are issues of economies of scale. Doing this both from a regulatory and a systems side is expensive. And we're much better off, we think, doing it once and trying to cover everything.

So as I suggested, it's a two-prong strategy. There's a systems side that we'll talk about a little bit - the central exchange system, which is a single reporting portal to EPA. And then there's the legal side, which we're of course going to focus on here today, the Cross Media Electronic Reporting and Record-keeping Rule. You can see that's where the acronym came from, CROMERRR. So I'll call it CROMERRR from now on, but that's what I mean.

It's worth saying a little bit about why we need a rule. And some people might think well you've got GPEA, that this Government Paperwork Elimination Act, but GPEA doesn't really override existing statutes and regulations. So to the extent that they refer to paper, or impose requirements that imply paper, GPEA doesn't address that. That requires some sort of regulatory action. And in addition, GPEA leaves federal agencies to determine on their own how and where to implement electronic reporting and record-keeping. So again, we need to do something affirmative in a form of a rulemaking, to spell that out in the case of EPA programs.

I guess the other concern, and it's one that I think is pretty evident throughout the proposed rule that you've read, is that among other things, these compliance reports and records that we're concerned with are legal documents. And we want to make sure that as we convert it to the electronic environment, these legal documents electronically can play the same role that they historically played on paper. And that requires certain standards. And that's partly what the rule is aimed at providing.

So, in terms of applicability, the rule is quite broad but it doesn't cover everything. It applies to regulated companies reporting to EPA. It applies to regulated companies

reporting to states. It applies to regulated companies maintaining compliance records, whether this is directly under EPA program or under some sort of state or local program. And it also applies to states that are implementing electronic reporting and record-keeping programs under their EPA authorization. So that's what the rule, that's who the rule applies to.

A couple of cases where the rule does not apply, however: It doesn't apply to the interaction between states and EPA as we exchange information between each other. Those are administrative relationships; they are not governed by this regulation, or probably not by any other. Similarly, the rule does not apply to current reporting that occurs using some sort of magnetic medium, like a diskette or a CD or a tape.

I know there are a lot of programs, particularly at the state level, that take reports on diskettes. CROMERRR does not affect those; it does not address those. So those will remain as they are.

Okay, let's turn to the general approach. On the electronic reporting side, the general approach is to require the use of a specified system that is managed or provided by the environmental agency that receives the report rather than specifying technologies and procedures in the rule.

The rule really doesn't get into the issue of what technologies or procedures have to be used. It just says you've got to report to a specific system. And the idea then is to let the design of the system determine the technologies and procedures that you've got to use in a particular case. And we think that if we design our systems correctly, that will ensure that the reporting meets the standards that we need to make them legally viable. So that's the general approach to electronic reporting.

In the case of electronic record-keeping, we also try to stay technology neutral to the greatest extent possible by identifying general criteria for electronic records to ensure their integrity, authenticity and to keep them from being repudiated at some point. The benefits of this approach, we think, are that it gives us a lot of flexibility to change as the technology changes.

One of the things that we learned early on, in earlier attempts to write a rule that were more technology specific, is that by the time we were ready to publish a proposal, the technology that we were providing for was already out of date. And we have no guarantee that that won't happen again and again and again. So we really wanted to keep technology out of the rule.

And that means that if something new and wonderful comes along, for electronic reporting, for electronic transactions, we can introduce that by changing our systems, but we won't have to go back and change the rule itself. So I think that's a good thing. We think that this will give us a simpler and shorter, and I put in parenthesis quicker, I don't know we'll see if it's quicker, it's not as quick as we hoped, rule making because again it's not so complicated. If we get into the nitty-gritty of having to specify particular technologies and procedures, it gets to be a very long and complicated rule. And we're trying to stay away from that.

And again, the reliance is really on the EPA or the state system to make things work right, rather than trying to get companies to interpret and understand complex technical specifications in the rules. And we think that that will make life easier for people. At least, that's the hope.

The core rule provisions. This in general is what the rule tries to do. First of all, maybe in some ways most important, it removes sort of with one sweep all the current obstacles in the Code of Federal Regulations to electronic reporting and record-keeping, whether they're explicit or whether they're implicit just in use of terms that seem to imply paper. These are all swept away. So that's one thing

that CROMERRR does.

Again, on the electronic reporting side, it requires that electronic reports be submitted to EPA systems or to EPA approved state systems. And it sets performance based criteria for the state electronic reporting system. It sets standards for electronic records. And finally, it ties the approval of state systems to the existing legal structure ... it's mainly a regulatory structure ... that is involved in EPA approving the state programs which we have to oversee, given our statutory mandates. So we don't create any new authority to oversee state programs; we simply say that where a state's introduction of electronic reporting or record-keeping would require EPA approval, these are the standards and criteria that a state has to satisfy.

So that's sort of an overview of the rule. In terms of the structure, what we've done is actually create a new part of 40 CFR Part 3, and currently the rule would create four subparts. Subpart A is general provisions; Subpart B is electronic reporting to EPA; Subpart C is electronic reporting under EPA programs; Subpart D is electronic reporting and record-keeping under EPA approved state programs. That's where we get into the business of approving state programs where we need to.

Let me just conclude this overview by talking a little bit about the general provisions and then we'll go on and talk about electronic reporting to EPA. The general provisions, are really pretty simple and straightforward. Basically, the rule says that we allow electronic reporting and record-keeping under any EPA program. Once the program announces that it is ready to receive electronic reports or allow electronic recordkeeping, and so long as the electronic reporting or recordkeeping satisfies the requirements in the rule.

So the idea is that without any additional rulemaking per se, any EPA program that is ready to start accepting electronic reports or allow electronic recordkeeping, can turn it on for their program by simply publishing a notice in the Federal Register. So there doesn't have to be any additional rulemaking. And we don't know right now exactly how many programs will be ready to turn the switch when the rule is final, but our hope is that many or most of them in fact will be, so that the wait between the publication of CROMERRR and actually implementing electronic reporting and recordkeeping will be very very small. So those are the general provisions.

And now we can turn to electronic reporting to EPA, but since we have a couple of minutes, I could take any questions

people might have on just this overview, if there are any.

Barbara Foy: Good morning. My name is Barbara Foy and I'm here from Monsanto Company. And I'm also here as a representative of SQA Society of Quality Assurance, an organization that has a lot of members who are reporters to the EPA. And my question initially is about the statement up on the slide, once the program announces that it's ready to allow electronic record-keeping.

And my question about that is that currently, a lot of companies like ours are already keeping records electronically. And so there's been some requests for clarification on whether what we're currently doing is recognized and whether there will be some change when these kinds of announcements are made.

David Schwarz: That's a good question. I think that nothing we are saying in the rule is meant to imply that we don't recognize existing records being maintained electronically. I think, well we'll talk more about this when we talk about electronic record-keeping. When we wrote the proposal, I think we vastly underestimated the amount of electronic record-keeping currently occurring in the regulated community. And we realize that this is an issue with the rule. So it may in some way or another I think this particular element of the

proposal is going to have to be adjusted. And exactly what that adjustment will be, you know I think we'll just have to work out. But we recognize that there's a problem here.

Johannes Corley: Hi, I'm Johanna Scorley. I'm from IR4 headquarters at Rutgers University. My question is, is this rule mandatory, or is it purely voluntary as it is specified as I've read it in that if we keep paper records, do we have to keep electronic records?

David Schwarz: I know where this question is going. I think that depends. I mean I think that may depend on how one reads our definition of electronic records. The intention, again when we wrote the record-keeping provisions, was not to force people into the category of electronic record-keeping against their will and against everyone's intention. It's been pointed out to us that in some cases, our definition may have that consequence and we're, it's another area that we're concerned about.

Our intention, and we have to think about how to adjust the rule to accurately reflect this intention, is that we certainly do not want to force anyone to keep records electronically. That we think is a matter of company or facility choice. So the intention is that that remain a voluntary decision.

If the decision is to keep records electronically or to report electronically, then the standards in the rule become mandatory in those cases. In other words, we wouldn't recognize those reports or records as satisfying EPA requirements unless they satisfied the standards in the rule. But the more fundamental issue of whether you're keeping records or reporting on paper or electronically, that we intend a matter of choice.

Dick Lowery: Dick Lowery with British Petroleum. I'd like to take the question to the opposite side of just looking and wondering is there really anybody out there, other than maybe a couple of ma and pa operations, that has no electronic data as you define it? In other words, they have no computer, they have no voicemail to a managed system that has a computer. They're just totally free and they're total paper.

The other side would be is, people may decide wow, if I don't go electronic, or I don't like the electronic side in containment here, it's too structured, or too constrained, what I would like to do then is put it all on paper. And I know we have data in our facilities that originate from a computer operation. Some electronic device that measures something that gives a piece of data, and if I put that on a piece of paper, does that make it a paper number? It is a

computer number, an electronic digital value that was stored someplace before I put it on paper, and I can't really separate the two and go all paper.

In today's computer age, my comment is, I'll be curious as this thing develops this afternoon, is there anybody that is totally paper with no electronic at all that would come under this rule?

David Schwarz: That sounded more like a comment than a question.

Dick Lowery: Well I'm looking for a response this afternoon to fill that gap.

Subpart B - Electronic Reporting to EPA:

David Schwarz: Okay. Maybe we should move on to the electronic reporting part. We'll come back to electronic records. Actually it will be later this morning, in fact right after the break. Or maybe sooner depending on whether or not there are comments on electronic reporting.

David Schwarz: Okay, we'll come back to some of these very interesting questions, I'm sure, within the hour perhaps. But let's talk a little bit about electronic reporting to EPA. The general provisions for submitting an electronic document

to EPA is first of all, that EPA has to announce for the particular report, say something like a discharge monitoring report, that we're ready to take it electronically. And then, the other requirement basically is that the electronic document has to be submitted to an EPA approved system, or an EPA system. And it has to bear a valid electronic signature.

And that pretty much is the long and short of it, to unpack it a little bit generally, the rule requires the use of our central exchange system or some other specified system. It doesn't go beyond that in terms of specifying technologies or procedures. You know, that in a sense will be determined by the way that central data exchange (CDX) is built and what is required to interact with it. And we do talk quite a bit about that in the preamble and I'll get to that in just a moment.

That will determine really what the electronic reporting interaction is like. And as I said earlier, as technologies change, we can change the central data exchange and upgrade it, move it along as the technology evolves, that will not change the fundamental rule here, fortunately. The only thing that's required is that we will have to provide you with notice that we're making those changes and I'll get to that in a minute.

For electronic signatures, really the only requirement is that they have to be signatures that we can validate. And again, that will be determined partly by how we set up CDX, what kind of signatures we plan to accept. And we specified that the signatures will have the legal force of a written signature.

So that's pretty much what's in that subpart B. Since however we do place a lot of weight on the use of the central data exchange, I thought I'd say a little bit about that. We do describe it extensively in the preamble. The rule and CDX, we like to say, are kind of bound at the hip. The rule in a way sets many of the requirements for the system, as a system for receiving compliance reports. And it relies on the system by and large to ensure that what we're going to get are going to be legally viable electronic transactions.

The preamble on the proposal provides substantial public notice on how we currently, or currently as of when we wrote that, plan to build CDX and operate it. And to the extent that we change that over the years, and I'm sure we will as time goes on, the rule requires that we provide public notice, particularly in cases where the change is going to affect how it works for you. So we're not just going to change it willy nilly.

The next slide is an early conceptual picture of the system. I don't know how helpful it is, but the idea generally is that we would have what's sometimes referred to as an enterprise wide platform for accepting submissions from companies and states that would probably be able to accept them in a variety of formats, some standard, some non-standard. We'd also support Web-enabled transactions, those forms that you fill out online. And the system would also support an electronic signature process which would include validation.

If we use a public key infrastructure based digital signatures, we would probably try to use those being adopted government-wide, under something called ASIS and I can't remember what ASIS stands for, but it's meant to provide certificates that would ultimately be valid for interaction with any federal agency. And that seems to us like a good idea because that way we won't have to manage a bunch of different certificates.

And the system would provide a way of interacting with that. It would interact with our legacy systems. It would be kind of a data pass through. For example, if you submitted a discharge monitoring report in some sort of batch format, like an Excel spreadsheet or in XML format, the system would

translate that and pass it through to our permits compliance system. So I mean it's currently operating as a sort of interim system. We are taking data uploads from the states. We are taking submissions in certain cases, for example the Toxic Release Inventory. I think we took about a thousand submissiona.

Joe Retzer: About a fifth of the companies were invited to, given the opportunity to electronically report it.

David Schwarz: And as we move forward with CROMERRR, and as we tighten up some of the details, adjust some of the requirements, we'll go forward over the next two years and build this into the production system. It will manage all the electronic reporting, we hope, between companies and EPA. So that's CDX in general.

Why we're taking this approach, well, probably a big reason, is simply economies of scale. You know, a system like that is complicated. It needs to be managed; it's expensive to build. And we just want to do it once. So that's one reason. We think that it will simplify and standardize the agency's management of these electronic transactions. And it will give us an increased ability to integrate and distribute what we get to the programs to the public to interested companies and so on. It will be just much more efficient.

I think from the perspective of people outside the agency, taking this approach will also be beneficial. It will give you a consistent uniform user interface and a consistent, sufficient procedures. You won't have to do it 10 or 20 different ways if you deal with 10 or 20 different EPA programs. We're going to try to make it as uniform as possible. And I think, particularly for companies that have high volume submissions across the budget programs, I think that will enhance the ability, your ability to automate your interaction with EPA to the extent that you want to down the road. It will create that opportunity anyway. So those are some of the reasons why we're taking this approach.

I guess the other thing I should talk a little bit about is the CDX registration process, that is, what happens when you initially sign up as a user of this system to submit reports to EPA. And right now we're thinking about a two phased process. One is just an interaction between you and us, where you basically sign up to use the system. And you get an account and password and a log on ID. And we create some kind of section of our Web site for you, that has controlled access, that is your mailbox on the system. So that's one part of the registration process.

The other part would be for the assignment of an

electronic signature. If we do use public key infrastructure certificates, we don't plan to be the certificate authority. And we don't plan to take whatever data is required to establish your identity for purposes of issuing a certificate. That would be a commercial enterprise. And we will, as a part of the registration process, kind of link you to them, but beyond that, that will be an interaction between you and whatever company (for example, VeriSign or Entrust) that actually issues you your certificate.

So that would be the two phases of the process. One is the registration with us; the other is the obtaining of your digital certificate. And that's how we're thinking about that.

Eric Van Gestel: Eric Van Gestel, CEO of Enverity Corporation and we actually build enterprise software solutions. So it's very important for me to know when the types of data, when it would be known what types of data could be received by the system, so that we make sure that we don't build something that would be obsolete. So my question is two fold. One, and I recognize that it's a little tough; it depends on what kind of comments you get and whether the proposed rule goes final and all that, but do you have a rough idea of when the kind of the technical specifications of the CDX will be available and

is there any plan for a pilot program, for a number of companies and perhaps municipalities to participate in a first stage as kind of a beta test?

Joe Retzer: We actually have been doing a fair amount of testing as David mentioned. We have sort of an interim central data exchange that's up and operating now. There's two major types of reporting that are coming in. One, as David mentioned, the vast majority of the reports under EPA regulations are received by states. And then we get huge uploads of that data from states. So one thing we're doing is working on the state to EPA, and EPA to state interactions. And we now have done that for a couple of programs there, and we're working on bringing in the others.

The other is the direct reporting to EPA. And that's very important to us but there's less of that. What we have done there so far is worked with the Toxic Release Inventory program, and we've actually tested a couple of signature approaches there. We did a public key infrastructure (PKI) test just this summer as well as another approach where people used a digital signature, not a PKI one, but also mailed us a paper certification letter.

For next year, since we probably won't have the regulation finally in place and the collection is June and the

information technology (IT) decisions had to be made this fall, basically for that program is pushing this new TRI ME CD software and we have actually built electronic reporting into that.

So just like on your tax software, TurboTax or whatever, where you can just go push on a button and say, if you want to send it electronically, this is what you need to do. For TRI reporters, next year, they use TRI-ME. They'll simply be able to do that. If they want to send it through CDX, all they have to do is follow the directions that are already built into the software to report electronically.

We're also doing a few tests for a couple of reports on the, under the Toxic Substances Control Act (TSCA) program. Health and safety studies are some, and I think it's the PMN cover sheets, the non-confidential business information (CBI) part of that program, to start testing some of that. So we do have testing underway.

In response to the other part of your question about the broad specifications for CDX, we have made a decision for purchasing the basic components of the permanent central data exchange. We've gone to the GSA millennia contract, which has maybe nine or ten of the largest software integrators on it. We'll be going out with our request for proposal (RfP) for

that around January. And that's actually an interesting contract because folks, even though there's I think only nine or ten primary contractors on the GSA contract, it's very easy for them to partner with a wide range of other firms when they come in for their particular proposal to us.

David Schwarz: Let me add one thing that, I don't know if you noticed this. The CDX design specifications, as of about maybe a year ago, I think are in the docket. They're in the docket for the rule.

So unfortunately I don't know that that's available electronically, although if you want that electronically, we might be able to provide it to you. Some of the things are still a little bit in flux, of course, because the requirement, our concept of the requirements is still somewhat in flux. But it will give you at least a basic idea of what our thinking is, the general architecture and so on. So you could have that.

Deanna Heffron: Deanna Heffron from Ondeo Nalco Company. I had a quick question regarding the certificate authority and the firm that's going to be identified for handling that portion. Is that going to be some sort of partnership set up similar to Cass with the registry service for identifying the naming and such for PMNs where there's one individual and we

have to set up ahead of time all of the fees and the payments and such. Or is this going to be some sidebar multiple organizations that will be handling this where you have your options for fees or renewals or anything of that format?

David Schwarz: Yes, the basic idea for this is to give you a digital certificate that you can use for signing reports to EPA. And it's basically a part of the registration, not like pesticide registration, but individual registration for you. And one of the reasons that we're doing it outside of EPA is that the goal under this digital certificate program across government is that these certificates will be able to be used if you have a report to FDA and to EPA and to other federal agencies. Eventually, you'll be able to use that same certificate across all federal agencies.

We're also starting to look at next year, there are a number of states that are starting to be interested in public key infrastructure- (PKI-) based systems for signatures. Illinois is one of them. And we're looking at working with some states, including Illinois, for using cross authentication for those certificates. So if you got a digital certificate for Illinois, you'd be able to use it for EPA and vice versa.

And the best way to do that, we think, is not to have EPA

try and manage those certificates, but rather these third party organizations that basically will do that as part of their business. That's what they're about.

Deanna Heffron: Would that be partnering with one key firm that would be handling all of those issues across the board, or will they be, do you envision having multiple firms?

David Schwarz: EPA would probably be working with one firm, but other agencies might work with other firms. In other words, they'll all agree to use compatible software approaches so that the certificates will be able to work with each other.

Male Participant: Has EPA identified a firm? If so, whom do we contact?

Joe Retzer: No.

Male Participant: Will there be a fee charged by this firm?

Joe Retzer: No, the way it goes is, as David suggested, is you'll come to central data exchange to register. And if that particular program requires you to get a digital certificate, because not all programs will, but if that program requires you to get a digital certificate, it will just do that through the CDX site. It will take you to the other site. That site will ask you for some information, and you'll get back a digital certificate within a few days. It will check whatever information you give that basically guarantees that it's you

that they're dealing with.

Male Participant: Sorry. Is there a Web site...

Joe Retzer: ... rule is that as EPA is ready to go, because you know, shifting a program from paper to electronic, and doing the software so we can translate it and get the data actually back into the program system. Each program has a little bit different kind of requirements in how they want to operate. That takes a fair amount of work, so as each program is ready to go, they will announce, you will be invited to come to the site and register.

Probably the biggest direct reporting program we have now, and kind of looking at the list of who signed up it probably doesn't affect you, is one that involves reporting of drinking water laboratory reports. And that involves the folks from the laboratories registering, folks from states registering, and folks from the local communities where the water samples have come from registering. And it's a fairly complicated and pretty ingenious system.

The laboratories send in data; they register, send in data to EPA. Then the localities and states can log on in a limited access site to view that data and okay it before it actually goes into the database. So there's three sets of people actually who are registering for that system.

So we only are sort of opening the doors to registration when we get each program ready to go. And the only ones right now that we have that are direct reporting to EPA are some people in the TRI program this year. Next year if you use TRI ME, the program software, everybody can report electronically, that does TRI directly. We're also starting some of that working with the TSCA program, for some of those reports. It's just still in the testing stage.

So we've invited a few testers to work with us on those reports.

Dick Lowery: Dick Lowery, BP. Again, you may get into it when you go into more details. But on the signature, I'm not familiar with it in detail. Is the signature certificate, is that quite mobile? If I had one, could I go to my laptop here, or if I'm doing it from home, or I'm traveling and I'm on the company computer. Or is it tied to a specific C drive on a computer?

David Schwarz: I think the way, it can be a number of things, but I think the way we're thinking of it right now is having it tied to a C drive of a particular computer.

Dick Lowery: So if my manager has a desktop he needs to carry it with him? I mean, we're in a mobile society and we're in an electronic society.

David Schwarz: Well as far as the rule is concerned, as opposed to the specific design of CDX, I mean, that issue just isn't addressed. Either way would be okay. I think our own thought right now is to tie it to a particular computer and to make it a software-based certificate as opposed to a token based certificate like a Smart Card.

My sense, based on some of the discussions I've had with the enforcement people who care about this is that a token, based approach would give you more mobility because you could use it in any machine that was capable of reading it. But a software-based approach would be the machine that the software was on.

Male Participant: (inaudible)

David Schwarz: Yes, I mean ...

Michael LeDesma: Probably for some applications. Again, we see some distinction between those things where signature seems to be critically important for the enforcement community and for those who are likely to make sure that we have the PKI based approach. There are other things for example, these live drinking water laboratory reports that come in to us. They never had signatures on paper. They just had come from such and such lab. So for them personal identification number (PIN) authentication is fine.

So it's probably going to depend a lot on the individual reports. In some cases, it may well depend on ... see, because we typically will work with some members of the reporting community before we put the particular application in. It may be, particularly as we move toward getting CBI related reports, that industry is going to demand the very most secure kind of thing, not portability. We'll just have to see as we move forward to those. As David mentioned, those kinds of things really aren't a function of the rule. Those are the function of the system that we build.

Craig Blackham: I'm Craig Blackham and I work with O2 Blue and we provide electronic reporting systems for states, actually Web-based electronic reporting systems. When you talk about certificate authorities and PKI are you talking about X.509 digital certificates? Is that the standard that you're kind of leaning toward?

David Schwarz: Yes.

Craig Black: Okay. Are you looking at using an XML-based data standard for the CDX system?

David Schwarz: Yes.

Craig Black: You are?

David Schwarz: Well, not exclusively but we're looking to support that.

Craig Black: Okay. If I can make a comment also, we in building some of our application for states, we have found that digital certificates have in some cases been a barrier to participation for companies. And simply because it's, in many cases, well it's like filing your taxes. I file mine, a lot of people file their taxes electronically. But I think that if the IRS required digital certificates in order to participate in that, it would have a lot lower participation rate, just something to think about as you continue.

I would try and make this digital certificate requirements as lenient as possible. And I can actually help answer the question about the mobility. And X.509 digital certificate can, it's a software certificate, but it can reside on a USV token, so the certificate's the same whether it's on your hard drive or it's on a key fob or it's on a Smart Card. So you can have absolute mobility with an X.509 certificate.

David Schwarz: Can I ask you, could you say a little bit more about why you find the digital certificate to be a barrier?

Craig Black: Absolutely. The, what we have found is that the process, the authentication process required by most certificate authorities is such that it makes it, for example if I actually have a couple of digital certificates. And for

one of them, I had to actually, I had to physically go there and authenticate myself with two forms of ID. And I was actually quite interested in obtaining one. So I would have gone to whatever length necessary to obtain the digital certificate because I need them to actually experiment and develop with.

I think a company who can make the decision to either file the reports on paper the way they always have done, or jump through a lot of hurdles to file electronically, nine times out of ten they're going to choose to do it the way they're doing. Because they're comfortable with it and it doesn't require a lot of extra steps. If the certificate authority, if you can issue some sort of certificate policy and make the authentication a little less stringent, because you already know information about companies and individuals that are already filing with you.

But most certificate authorities, because they are guaranteeing the authenticity or the identity of the certificate holder, will require some sort of proof of identity; whether it's a credit card and/or drivers license. I actually had one certificate that I had to show, I had to fax in a copy of my passport, my drivers license and a credit card, and I had to have the statement sheet notarized by a

notary public in order to obtain the certificate. And that type of requirement to participate in obtaining a certificate, is stringent. I don't, I just don't, we don't have a high rate of willingness to do that in order to file electronically.

David Schwarz: Could I ask you an involved question? I guess, I seem to hear you saying that if we went with a certificate issuance that involves a very low level of authentication or identity proofing that that might not be such a barrier.

Craig Black: That's correct. That's correct. If you had a certificate authority that would be willing to issue certificates on loose authentication basis.

David Schwarz: Well, I think, I mean, I guess our feeling is that we're the customer and we would want to drive that train and not have the certificate authority dictate that.

Male Participant: I will be extremely concerned about somebody issuing a certificate authority on very loose identification.

Barbara Foy: I just had one more comment and I wanted to give an example before I asked my question. For a company that comes to EPA for approvals for new products, it's not a simple short form kind of reporting format that we would envision.

But it would be the submission of quite a bit of information, perhaps in volumes, and organized in such a way ... but it would be a large amount of information that might be submitted. And as I understand the CDX system, if you want that to take all documentation that comes to EPA, those kinds of large submissions also would come in through your CDX system.

For that kind of a process, where multiple documents are required within those documents, multiple individuals' signatures are required as part of the underlying EPA regulation. And so that kind of a submission through CDX would involve many documents with many signatures, as required by the underlying law. So my question is, does the CDX signature process that you're envisioning, that you're working to put in place, envision that complicated of a type of document that you might be receiving where you'll have a variety of individual signatures associated with one submission?

David Schwarz: That's a good question. And it's one that we've been wrestling with a little bit. I guess the answer is that currently we haven't really thought through that process. And we realize that we need to. So I very much encourage you to, well, your example will be recorded here but if you're

submitting comments, I think that's a good example to site, you know, as you're raising the issue. I think we need to address that. I think that, I don't think that there's anything in the regulation itself, the regulation criteria, that prohibits that, but I still think we need to think through the implementation.

Michael LeDesma: Let me just add to that. As far as I know, if you're talking about things where companies are currently submitting data either on paper or on magnetic media, that we don't see that necessarily changing in the short term. We're trying to address those things where there's a major advantage for being able to submit electronically, not using magnetic media, and it's not clear that there's a huge advantage for being able to transmit over the wires, which are handing in in a CD, if you're just doing it once every several months when you come in with a new product.

Our initial focus is on those things such as discharge monitoring reports (DMRs) or things where there's masses of data coming in, but in smaller kinds of chunks, and people could sign the file.

Tom Neumann: My name is Tom Neumann from Monsanto. I want to extend Barb's comments to include work that's done at contract laboratories. We do a lot of work outside and we would be

getting documents in that would have signature requirements on those. We would not have access to electronic signature in that case from other companies. How do you plan to address that particular issue?

David Schwarz: I guess it depends. Are the signatures on the documents that you get signatures that are required ...

Tom Neumann: Study director signatures or sponsor signatures, that type of thing.

David Schwarz: So these are, these are signatures that are required by EPA to be on the document?

Tom Neumann: That's correct.

David Schwarz: I think that's very much like the case that the previous speaker was talking about. I mean, I don't have an answer for you today. It's certainly the kind of case that we either need to keep as Joe was saying on a mag medium kind of submission, or we need to think through the implementation.

Male Participant: Just a comment on this. I don't know, this is probably going to be quite open to discussion here, but after the comments of others, when I submit a report that's for a (inaudible) of residue study, for a registration (inaudible) often you use. For that, we have, currently we have, everything on paper so we have paper signatures of the laboratory research director, the analyst and possibly some of

the chemists involved in the study. Then we have the study director signature, we have the sponsor signature, a submitter signature if different from the study director, and QA signature, so there are several signatures on this.

What I thought was, if EPA could go about just having a certificate of authority to the submitting person, and each organization then maintains its own files, digital files, on electronic signatures, something of that effect. I'm just throwing this out, open to comment.

David Schwarz: Is there any comment on that idea or other comments?

Subpart C - Electronic Record-keeping under EPA Programs

David Schwarz: Okay, all right. Let's talk about what's probably everyone's favorite topic, which is electronic record-keeping.

The goals of electronic record-keeping are first of all, to allow industry to keep electronic records in lieu of paper records, to the extent that current regulations provide an obstacle to this. And for EPA, to ensure that the electronic records maintained by regulated companies are reliable and trustworthy and are available to EPA or to state agencies as

required by the regulatory programs. So those are the overall goals.

The e-records approach in general: The scope applies again to recordkeeping by regulated entities under all EPA and all EPA-authorized state programs, although we do leave room in the rule for exceptions. We don't list any in the proposal. We don't list any exceptions or exemptions in the current proposal but there's a space for them, should that prove to be a good idea. And the approach again is general function-based criteria for electronic records that we hope, or had hoped, would assure integrity, authenticity and non-repudiation. We are also concerned about being consistent with existing compliance practices.

For example, under the good automated laboratory practices program that addresses TSCA and FIFRA, and with existing electronic records regulations, and I guess our main model, since this was really all that has been out there, is the Food and Drug Administration regulations. And we have tried to be consistent with FDA to the extent that a company subject to both FDA, that is Food and Drug Administration, and EPA regulations would comply with EPA record-keeping standards, if they were complying with FDA record-keeping standards. Our standards, I don't think, are as stringent as

FDA's but they are compatible with them.

Just conceptually, in terms of the difference between our approach to electronic reporting and electronic record-keeping: In the case of electronic reporting, since we're talking about a transaction between companies and a state or federal agency, we in that case could rely on the characteristics of the EPA or state-controlled system.

In the case of electronic recordkeeping, almost by definition, we're talking about things that don't interact with us. So we're addressing things that go on in company systems, that is a part of the business practices of the company. So there's a kind of a different problem in terms of setting standards.

Anyway, in terms of the electronic record-keeping provisions, and we've talked about this a little bit earlier, the general provision is that we would allow electronic record-keeping under any EPA program once EPA announces for that program that it is ready to allow electronic record-keeping. And we would allow electronic record-keeping so long as the electronic record is generated and maintained by an electronic record-keeping system that meets the criteria. And it's the criteria in Subpart C that provides the substantive requirements.

And the criteria are laid out there. I don't know that I'm going to read them all off to you, but you can read them. Certainly a couple of these we know are controversial, particularly the requirement that there be an audit trail and the requirement that archiving include the audit trail and preserve the audit trail and other related information if the records are migrated to a new system.

There are some special criteria in the case where the e-records are signed. And they include indicating enough information about the signature so that we know what the signature means, for example, whether it was a signature of the reviewer, an approver, et cetera. And we need to be able to link the electronic signature that's a part of the record to the electronic record in a way that the link cannot be lost. The signature has to be bound to the record in some way.

And generally the electronic signature information that we specify has to be subject to the same controls as the electronic records generally. So those, in a nutshell, are the criteria for electronic records and we might as well go ahead to the comments.

Johannes Corley: Johannes Corley IR4 headquarters, Rutgers University. Come back to the point, which I started with in

the first question. I think we need to talk about the definition of data because as a gentleman here just remarked, a lot of our data is generated on computers. So is it the zeros and ones that the computer generates that would be the original raw data, or would ... if the organization was to define it, the paper record that is printed out, initialed and dated, suffice as the original raw data? I think we need some guidance on that issue for starters.

Joe Retzer: I just have a question. This is the case where the data is generated electronically but then printed, right?

Johannes Corley: Correct. Let me explain. In most cases nowadays, data is generated electronically. I had a discussion with some of our labs a few days ago. And they were reading this and of course a lot of them didn't understand it completely, and said, you know what? We're going to go out and buy strip chart recorders. But that's beside the point.

I think we need to define ... does EPA have any comment what would be the original? Would you like ... I mean, FDA has interpreted it in some ways. I don't know what's EPA's comments.

David Schwarz: I don't know that we have a comment as to what is the original. I think that we become aware of the fact

that as the definition is written; a record generated as you describe it would probably fall within the scope of the electronic record-keeping requirements. And you might very well be required to maintain the original, the originally generated electronic record of ... and maintain it under these criteria.

Part of the answer, and this is one of the things that makes the subject difficult, may depend on the program specific regulatory definitions of what records are required to be maintained. And in some cases, the regulations are quite specific, that the originally generated raw data is part of what needs to be maintained. In other cases, this is not specified. And that of course would have to determine the answer as well.

So I can't give you an across the board answer, but we do recognize that this is an area where we need to go back and sort things out.

Deanna Heffron: Deanna Heffron with Ondeo Nalco Company. I have a question or request for clarification for one of the items specified in the proposed rule. It stated in here that the audit trail documentation needs to be retained for a period at least as long as that required for the subject electronic records. So does that mean that there is potential

that the audit trail documentation would need to be required and retained for longer than the electronic record retention requirement?

David Schwarz: I don't know.

Michael LeDesma: I can't think of any instances in which that would be the case. I think we were, I think the language there was intended to allow folks to of course keep it longer if they thought it was important for business purposes. But I'm not sure I can answer that question across the board and say that that's going to be true in all cases.

I can't personally envision any instances within which we would invoke that provision to require that the audit data needed to be maintained longer than is required by the underlying record-keeping requirement in the program.

But I would encourage you to make that comment in writing so that we can, so that we can put that to our program folks and say is there ever any instance where you would want us to keep the audit, or require that the audit data be kept longer than the existing record-keeping requirement? My suspicion is the answer would be a resounding no, that the record-keeping requirement specifies the period of time that that's required for the record retention. I think there would frankly be no reason. I mean, the goal here is to create a parallel or an

equivalency between paper and electronic record-keeping. And not to exceed that equivalency.

Craig Black: Craig Black I'm with O2 Blue. It sounds like the data definitions for CDX have not yet been rigidly defined, is that the case?

David Schwarz: I think the definition that's causing us some trouble is the definition of an electronic record. And we, just to give you a little bit of history, in taking over FDA's overall approach to electronic record-keeping, we took over some of their definitions, as well. And I guess, in the light of comments that we've gotten, and reflection, we now feel that we need to reexamine some of this in the context of EPA programs.

But I think that's the kind of question that you've been hearing the last couple of minutes that goes back to what's the definition of an electronic record.

Craig Black: I think so. And I think that's what a lot of us here are interested in: what format do our electronic records need to be in in order to be submitted to CDX? And that's, what we software companies are concerned about.

David Schwarz: Let me just respond to that. I think that's a different question. The format specifications for sufficient submissions to CDX are not a part of the rule, per se.

They're a part of the implementation design of CDX. And we talk about some of the formats we're considering supporting in the preamble.

And they would include, I guess we mention standard EDI transaction sets under ANSI X.12 for example. We, I don't know if we mention this, but we've been considering accepting the output of Excel spreadsheets and probably some XML formatted files, whether standard or non-standard. I guess we'll see how that plays out, maybe some other things as well.

And I guess the one thing to bear in mind if you're looking at this as a software developer, is that the bulk of the data transaction volume is going to be with the state systems and your question, I think, really needs to consider what formats are the states going to recognize. Because they will be, within broad limits, free to make their own decisions about that.

So, what we're talking about now are records that are not transferred to us, but records as they're maintained by regulated companies. So it's a different question.

Craig Black: Okay, thank you.

Johannes Corley: Going back to the issue of records which are maintained by us: one of the problems that we would face if we're talking about the electronic record being the point of

generation of the data, we're not talking about simple programs that are very widely available like Excel and Word. We're talking about very, very instrument specific programs.

And even today, when they start standardizing all the computers, you know, we have either IBMs or MACs. You still have very program, instrument specific programs. So this, would this then involve archiving the entire computer or the software or the instrument? Because sometimes a computer may not run without being linked to the instrument. I know they're changing some of that now, but you know, I mean, this raises a whole different ... I'm just trying to raise some of the issues and ask what you'll think about this. Thanks.

David Schwarz: I think it's a good comment that you know, I hope that it's one that you put in writing as well. I guess part of the answer, I think, is going to be driven again by the requirements of the particular EPA program.

If for example, a monitoring report involves the maintenance of records, including the raw data that was used to generate the values of that report, like you know, paper world's strip charts. And if these need to be available under the regulation, these are not regulations that we write, but these are the regulations that we're trying to accommodate. If these, in the paper world, if they need to be available for

a certain number of years, you know, to be viewed by inspectors coming around to inspect whatever they inspect.

Then if you move to the electronic environment, I think you do have to consider the possibility that you know, if for example, you have an electronic counterpart of the paper record that's required, and it's only viewable or accessible by using the piece of equipment or software, then I think that will be an issue. And I don't think that will be an issue because of CROMERRR. I think that would be an issue because of the predicate regulation.

Barbara Foy: Barbara Foy, Monsanto. I had another question to follow up on the archiving aspect that CROMERRR would be applicable to. And it has to do with some unique circumstances with some of the EPA programs in that the EPA programs have some of the longest retention periods of any programs that have been covered by this kind of a regulation before. And I think it presents some unique challenges to the folks who have to comply with the archival requirements.

And as I understand the CROMERRR regulation, and the extent of process that would be involved in certifying that what you archive is authentic and contains all of the contextual information about the electronic record, and so on and so forth, it appears that what's being presented would be

an enormous change in the program that's currently going on in many EPA compliant companies.

And along with that would involve an enormous new expense for those companies. And so those concerns about the cost and the extensiveness of how to comply with this rule, combined with technology questions about is the technology really available at this time, to archive these records for this length of time, are there ways to do this? Is anyone able to demonstrate that they can actually comply with the requirements in CROMERRR as far as archiving is concerned?

It just raised a whole multitude of questions about archiving and the thought that came to me about that was that it, at some point, there would be a way to allow companies to transfer all of their electronic records to paper for archival purposes only. It might be a way that companies could even begin to conceive trying to keep good, complete, authentic records from electronic sources in a way that we might be able to imagine being able to comply with at this time.

It just seems like if one of the goals of CROMERRR is to be consistent with the Paperwork Elimination Act that when it comes to archiving, it certainly is not going to eliminate paperwork. Companies will, at least at that point, rely on paper records for archiving purposes. And it will actually

result in another process step, another attempt to archive in an electronic manner, but at this point in time, I can't imagine any company will rely on untested technology for archival purposes. They'll probably still back up and use paper copies for archiving purposes.

Joe Retzer: Okay, thank you. I think it might be helpful if, hopefully you'll make that comment written as David said. If you could be a little specific about your circumstances, for example, what the current requirement is in terms of number of years and how you handle ... this is, you're talking about pesticide registrations? I know it's a long retention, like 20, 40 years ...

Barbara Foy: The life of the product. This can be those 30 year, you mentioned 30 years ... those are those kinds of timelines.

Joe Retzer: So if you could maybe talk about how you're addressing that now, because I know a lot of that data is submitting electronically. And under the current circumstances whether you print that out after a certain number of years, or whatever, I think that would be really useful.

Barbara Foy: If I could make another comment, I'd like to go back to the, some of the discussion about the connection

between the definitions of an electronic record and the definition of raw data, for those EPA programs particularly in the FIFRA area. And I think if there's one area that it might really be very helpful for you folks to consider is exploring and discussing those connections more fully, as you develop responses to some of these questions.

Because the, there seems to be no doubt that the FIFRA GLP (phonetic) part of the agency has a very definite interpretation of raw data as being an electronic signal. If you're gathering data electronically, the raw data is the electronic signal and there seems to be no argument about that. And so in that case, when you connect that with CROMERRR, you will be required to comply with CROMERRR for those types of electronic records. And so you can go from that point back to the issue of, is this rule voluntary, and say if the only way to collect that information is through an electronic device, which is the case for many sophisticated analytical methods, that it is not voluntary. It is mandatory. All of the bells and whistles are included if you use the technology that's currently very much in practice.

Joe Retzer: I also have a question to ask the group to think about either here or not. One of, as David mentioned earlier, one of our primary purposes here in doing this rule was to

enable electronic activities, reporting or record-keeping, where current regulations prohibit it. And it seems like, in trying to do that, we you know, in the record-keeping area, we hit a lot of areas that people are already doing electronic stuff.

If anybody has any ideas or things that they want to let us know about, or areas on record-keeping where you now interpret the regulations as requiring you to do, keep paper records, and where that's a problem, where you'd not like to have to keep paper records, we'd like to hear specifically about that. Because that's one of the things we still don't want to lose as we move forward on this, is to make sure that if there are cases, as under the Government Paperwork Elimination Act, which is the focus on trying to enable electronic record-keeping where current regulations require paper. So if you have some ideas on any of those areas, in any of your work you're dealing with, we'd like to know about that.

Deanna Heffron: Actually I had a quick, hopefully quick and easy question for you. Deanna Heffron with Ondeo Nalco Company. In the section here for the, under the storage media issues, it had mentioned that there was going to be some criteria put in place for transferring of the electronic data

from one electronic media to another. Are those criteria also envisioned to imply for the transfer of data from one internal electronic system to another? In that regards, many companies have databases where they're retaining the information, so if the records are transferred from one database to another, where they're then further manipulated or stored or additional data is entered, are those transfer criteria going to apply in that case?

Joe Retzer: Just so I understand the question, you're not talking about migration from one system to another, but you're talking more about the case where you take the output of some kind of reading device and you put it into an Excel spreadsheet for data manipulation, or ...?

Deanna Heffron: Actually, it's transfer of raw data into say, an Excel spreadsheet, Oracle database, Access database, and migration from one computer system to another where certain companies may be employing multiple systems to currently comply, or to manage the data that they have on hand.

Joe Retzer: I think that's an area that we plan to do more analysis of. So that, whether we'll issue standards for that, or whether we'll decide that we want to use that analysis to restrict the scope of the criteria. I mean, I could imagine that being an outcome as well. So I don't know what the

outcome will be but we know that we need to look more closely at those kinds of scenarios. Does that answer your question?

Deanna Heffron: I guess I'm just trying to get a feel for if, in the rule, those criteria, the data transfer criteria was truly intended to apply to, say, transferring from CD ROM, or from a server onto, burning onto a CD, or electronic tape onto a CD, or from electronic to electronic database, one server to another server, another database.

Joe Retzer: I think it would. I think what we had in mind when we wrote the criteria was more the former than the latter, but what we discovered was that the latter also raises important issues.

Deanna Heffron: So then ...

Joe Retzer: I don't want to make you nervous. I mean, I don't think that the result will be the addition of yet additional more stringent criteria, but I think we need to understand better the, what the life of the data is, from raw data all the way to say, report, and try not to pick up things that we don't need to pick up.

Deanna Heffron: But if you were, in your analysis, determining that further supporting documentation, or whatever, is needed for the life of the data, would it meet the criteria as ... or would the criteria that's outlined in

the proposed rule apply to that data transfer, or would there be some additional or expanded criteria that would be forthcoming in the final rule?

Joe Retzer: I guess I'd have to say that I just don't know at this point. I think it's unlikely that there will be additional expanded criteria in the final rule. But I think until we go back and reanalyze this area based on comments, which have been very helpful, it's hard to say exactly what we're going to be doing.

Bruce Carlson: Yes, Bruce Carlson. I'm with Illinois EPA Division of Legal Council. On this Subpart C, dealing with electronic record-keeping, where it refers to both electronic records and electronic documents, it seems to me one area where it's potentially ambiguous is that while electronic documents specifically excludes the magnetic media, electronic record is a much more broad term and it doesn't exclude electronic media, so the question would be then, whether these record-keeping requirements might be made applicable to both facilities and the states where they are doing reporting with regard to magnetic media.

Do you have an idea on that presently, or is that something you need to consider further in the final rule on this.

David Schwarz: Well, I have an idea. I don't know if it's the answer you're looking for or not. I think the distinction between electronic reporting and magnetic media submission, or mag media, makes sense in the context of reporting because we're talking about a vehicle for transfer. And you know, it's different if the data comes in over a network, and whether there's actually a physical object that you put in an envelope - a diskette or something - and send off to us. I think that's a clear distinction.

In the case of record-keeping, I mean the truth is that all electronic record-keeping, except for I suppose records directly in the random access memory of a computer, are in what one could refer to as mag media. So I don't know that there's the same distinction to be made. I think.

Dick Lowery: Dick Lowery with BP. Michael, you made a comment that the intent of CROMERRR was to not make electronic record-keeping any more ... I don't know if restrictive is the right word ... not to put any more criteria on electronic record-keeping than there currently is on the paper trail. And until CROMERRR was proposed, there was no specific criterion for the electronic form versus paper.

And again, as we were talking today, what I put on paper I may have gotten off electronically. And we're trying to

revisit, or will in the future, revisit what the definition of what data or electronic data is.

But let me ask the question. Are you really saying that for people out in the facilities that have a lot of electronic data on their computers, and they have it on paper or they put it on mag media or anything else, are you really saying that there is going to be absolutely no more restrictions or criteria put on top of storing that data or having that data electronically than there was before CROMERRR?

Michael LeDesma: Well, when I made the original comment, I was responding to a question about record retention periods, and whether an audit data would be required to be maintained for longer than the record itself, or longer than existing record-keeping requirements. I guess your question is more geared toward the overall burden of electronic record-keeping versus paper record-keeping.

I think the goal, or the intent, was to create an equivalence between electronic records and paper records. Now of course, as we're all learning here, electronic record-keeping, if it's to be done right, whatever that means, if it is basically to have a certain measure of forensic value, does entail some bells and whistles and there will be costs associated with that.

The task that we're all struggling with is trying to find the right balance between forensic integrity in a document, in an electronic document, and the cost associated with providing that degree of forensic integrity.

And the goal is to, again, create an equivalence. But I'm using the word equivalence intentionally because of course it's not possible to create an equal. The paper world and the electronic world are really apples and oranges. Because in the paper world you have, on the paper itself, a great deal of forensic information that isn't necessarily available in the electronic world if you don't provide for it.

So I can't say that we're talking about not requiring you to do things that you didn't have to do in the paper world. Again, all I'm saying is, and all I intended to say in response to the earlier question is that our goal is to provide some sort of equivalence.

Barbara Foy: Barbara Foy, Monsanto. I have a question about consistency between the FDA's electronic records requirements stated in their Part 11 rule, versus what CROMERRR might be proposing and how consistent those two might be particularly for companies that need to be compliant with both FDA and EPA electronic records and reporting requirements.

And the question that I had, or the example that I'll

give, is sort of a funny one. I was in a meeting where there was a compare and contrast presentation between Part 11 and CROMERRR being presented to a room full of people who almost exclusively only work with the FDA. And so they had experience with Part 11 and they were giving this presentation and the reaction at the end of the presentation was that they all wanted to work for companies that worked with the EPA because there were virtually no requirements described by CROMERRR.

And so, I thought that was ironic. And I had not heard that before, and certainly the people who are working, trying to be EPA compliant don't believe that that's the case with CROMERRR but I think it highlights the interpretation people have because the two regulations are written so differently. Whereas Part 11 has a lot of detail in it and more specific instruction about how to comply with those requirements, CROMERRR is written in a much different style with functional criteria described.

And so I think that if EPA proceeds with CROMERRR, and I can see the benefits of writing it in a way that's, as you described, technology neutral, or criteria-based, there are benefits to that. But the problem comes in when people try to take it home with them to their particular job and interpret

it.

If as you say, you're trying to be very consistent with the FDA Part 11 requirements, you perhaps may get more information or guidance on specifically the corresponding part of Part 11 and how that is perhaps one way that EPA reporting agencies can comply with CROMERRR. Draw a real item-by-item kind of comparison and say while this may not be the only way to comply with CROMERRR, it would be an acceptable way. So that people can easily make that translation between what they may currently be doing for the FDA and where that would fit in their attempt to comply with CROMERRR.

David Schwarz: Thanks. Interesting.

David Keyes: I'm Dave Keys from Dow Agra Sciences and I work in the quality assurance group. I handed to David a number of copies for you of my written comments. And I didn't know exactly what the format was and how you wanted me to just go through the highlights of the document. I don't, how did you want to handle that?

David Schwarz: Whatever you think would be most effective.

David Keyes: All right. Well I'll, you've got the documents in writing and I'll try and go through and hit the key points that I was trying to make. The direction of CROMERRR is obviously critical to Dow Agra Sciences and the rest of the

agricultural chemical industry, as well as many EPA entities.

Mark Duvall, for the legal counsel for the Dow Chemical Company, presented his testimony to you at the Washington DC meeting, and I wanted to go on record to support everything that he said. And at this meeting, I wanted to cover some of the real life examples of the impact this would have on us in the agricultural chemistry industry.

We believe EPA should sever the record-keeping provisions and withdraw them for further analysis. And the reasons are that CROMERRR although presented as voluntary, as we've said, many people have stated here, applies to any EPA-captured record maintained on a computerized system. Therefore, it would be a mandatory thing, not voluntary.

Another point would be legacy systems would therefore have to be refitted or new systems purchased to meet CROMERRR requirements. In many field situations, certified systems to meet the proposed record-keeping requirements do not exist. Another point is the costs in retrofitting or purchasing new systems have been grossly underestimated.

Another topic I wanted to touch on was the Organization of Economic Cooperation and Development (OECD)comment that there were no other guidance things, but there is. We have tremendous involvement with OECD and they do have guidance on

computerized systems. And they do allow for the definition of raw data to include computer and instrument printouts. Therefore, OECD allows flexibility in the definition in retention of raw data because the OECD GLP guideline studies are accepted by EPA.

The new record-keeping requirements would lead to a competitive disadvantage for U.S. based companies compared to their European competitors who are still able to use the paper version. Governmental efforts over the past years have been to harmonize requirements globally, not separate them.

GLP raw data for FIFRA studies has been brought up several times. It needs to be retained for the lifetime of the registration, which could be decades. Verified paper printouts of the raw data have always been the safest method of data retention for these long periods of time and any migration of these electronic records runs the actual risk of data loss or corruption. And data may need to be migrated several times over the lifetime of a registration.

I wanted to go through on the record-keeping part. Again, the mandatory versus voluntary choice. And CROMERRR indicates that a facility can choose to keep all the records electronically, but if the choice is made then all CROMERRR requirements apply. What is implicit is the choice in the

method of collecting the scientific or electronic data. And if an electronic sensor signal is captured, processed and stored or transmitted by an instrument, then the electronic record-keeping choice was made by default. If any data is generated or maintained on a computer then the record-keeping provisions would apply and printing out that data for purpose of record retention would not be allowable.

Electronic record-keeping has long been a necessary part of data collection and is essential in collecting many aspects of the required regulatory studies. Data collection in the laboratory and in the field requires these types of systems. Many of these requirements occur over 10 to 15, every 10 to 15 seconds, for long periods of time generating massive amounts of data which are collected and summarized for the time period for reporting. This required data collection could not be achieved in any practical sense without the use of computers. And since computerized data capture processing archival have been used for decades the statement that CROMERRR is totally voluntary is a failure of the agency to face reality and present a true impact of the proposed rule to regulated parties and the public.

I wanted to talk about the legacy systems. And just an example, this is part of our normal business, just in the

three laboratory areas that are adjacent to my office. I went around and counted them up, and we have 50 different stand-alone analytical instruments which are gas chromatographs, HPLC liquid simulation, GCMS balances robotics. These are integrated with PCs and printers, providing an immediate hard copy printout. They're approved by the operator, signed and dated. The paper data is maintained as the raw data and this has been an EPA-accepted procedure since GLPs became effective in agricultural areas, since 1989.

We have also approximately 130 separate instruments used for field studies which capture and store electronic data such as data loggers of weather stations, temperature monitoring systems, flow meters, soil sensors, survey equipment, water samplers, flow meters, hydro labs. Each of these would be considered a separate system of electronic data capture. And these types of systems are essential in conducting these short- and long-term field studies. The data could be collected in time, from seconds to hours and go over years for the length of the study.

I've also participated in some fumigation studies where the treated area is set up and monitored for various wind, weather, all the different conditions. These go around the clock and extend over long periods of time. Electronic data

collection is our only option.

We also have studies called runoff studies where you set up an entire field on a slope with all the electronic monitoring down at the bottom of a sloped portion of ground and you're waiting for this runoff event. You don't know when the storm is going to come and hit it and wash everything to where it's going. But once it does, it triggers the different systems through the use of these electronic things. We can't maintain people out there all the time, but once the event occurs then everything kicks in and collects the samples.

So, as I said, these things are critical in doing this kind of work. The current technology for these types of electronic data capture, although they meet GLP requirements, they do not have the capability to meet CROMERRR requirements. A little earlier I was showing David, I brought just as an example, a Hobo Temperature Monitor. And this is an electronic capture device that's very useful in monitoring temperatures in freezers and refrigerators, or you can send it along with samples to maintain or get a record of the temperature during the transport of samples. The data is captured, downloaded. It cannot be altered. And it's signed off and approved by their originator as raw data.

But this, so it meets GLP requirements, does not have the

capacity to have audit trails and the other things that you're asking for. So this is just an example of a small electronic capture device that would be impossible for meeting CROMERRR the standards.

I wanted to talk about the cost estimates and how I feel that these have been grossly underestimated. And the agency only considered reporting the storage of data in the cost benefit analysis, and ignored the direct or indirect capture of data from automated instruments or devices, data processing and the different types of computerized systems that go along with these activities. In addition, the agency did not address the different needs and requirements for each case, but instead used a one size fits all approach.

The scope of CROMERRR is extremely large and it sweeps across multiple environments, laboratory practices as well as non laboratory practices processes are affected by this rule. However, the cost of compliance in the non-GLP areas may be greater due to the different requirements in those areas.

The cost estimates attached to Mark Duvall's presentation when he handed it in to you in Washington, DC, estimated $10,000 per analytical instrument to retrofit software to meet CROMERRR requirements, if it was possible to do so. Otherwise, the entire instrument would need to be replaced

and, like I said, the example I gave here, the technology doesn't exist to do that.

So overall the estimate of, he had presented, was one million dollars per facility for getting all systems to be retrofitted or purchased to meet CROMERRR requirements. This far exceeds the $40,000 per facility cost estimated by EPA. And in our case, the one million dollars estimate would be low by a factor of five, since the above estimates were for ten users and twenty instruments. We have at least 180 instruments combined in the laboratory and field, and an estimated 50 users. In either case, the $40,000 estimate is off by orders of magnitude. This only estimates the cost for one aspect of our company and does not even reach the others, which would be potentially impacted by this.

I wanted to now touch about OECD. The key point in OECD is that it does allow the flexibility in defining raw data for each system and that computer instrument printouts are included in that definition. My current facts in the United Kingdom indicate the definition of print outs as raw data as common and used to meet the OECD requirements. Therefore, OECD allows flexibility in the definition and retention of raw data. Due to this difference, additional CROMERRR requirements would lead to a competitive disadvantage for

U.S.-based companies compared to their European competitors.

The OECD application of principles of GLP and computerized systems, Monograph 116, Section 5 indicates, and I quote, 'computerized systems operating in compliance with GLP principles may be associated with raw data in a variety of forms. For example, electronic storage media, computer or instrument printouts and microfilm fiche. It is necessary that the raw data are defined for each computerized system.'

Section 5 also states, 'where a system's obsolescence forces the need to transfer electronic raw data from one system to another, then the process must be well documented and its integrity verified. Where such migration is not practical, then the raw data must be transferred to another medium and this verified as an exact copy prior to any destruction of original electronic records.'

Another subject that has come up here a couple times is the archiving for long periods of time, and problems with the retention of magnetic media have existed since the use of computers. The accepted system under GLP has allowed the flexibility of defining raw data as electronic or verified hard copy printouts approved by the originators. Retention of the raw data to support FIFRA registrations must be kept for the duration of the registration lasting decades. Our record

retention policy is 75 years, and the only stable option has been paper print-outs.

Corruption of electronic records over time during migration to different media all have the high risk of data loss. Our only safe and permanent solution today is to maintain approved paper print-outs of the raw data and archive these in secure areas with proper environmental conditions to prevent deterioration of the records.

We recognize that electronic record-keeping cannot be safely implemented at this point in time. But although we are in support of future electronic record systems, that are fully safe and secure, for these important records, the CROMERRR proposal would force high-risk practices long before the appropriate instruments and software technology are ready.

We anticipate it would require at least five years from the start of a well-funded EPA initiative for validating commercial systems to be available to industries regulated by EPA. In some situations, it may never be possible to obtain changes, which would fulfill all requirements. In the interim, the record-keeping provision should be withdrawn.

So, in conclusion, the points that I've tried to hit are the record-keeping aspects are mandatory. Legacy systems would have to be retrofitted or new systems purchased. The

cost estimates are grossly underestimated. And as I said, OECD allows a definition of raw data as paper print-outs. And the archiving for decades or using multiple migrations could lead to actual data loss or corruption. So due to these reasons, we believe the record-keeping portion of CROMERRR should be severed and sent back for further analysis.

David Schwarz: I was wondering if I could ask Mr. Keyes a question. I'm wondering if we address the definition of raw data and adopted the OECD approach, would that, would that in your mind mitigate many of the objectionable features of our electronic record-keeping criteria?

David Keyes: I think that that would be a good move, to go that direction, and would go towards the harmonization that everybody has been trying to achieve. Because our studies are usually transferred globally under the memorandum of understanding with OECD, things are accepted between Europe and the United States, and that would be one significant thing. Because I think their flexibility of allowing the print outs of paper within that definition has allowed them to fulfill their requirements.

David Schwarz: Thanks.

Michael LeDesma: If I could add something. You know, as you say, Washington, DC, we heard similar recommendations that we

should sever the record-keeping provisions of the rule. And I would ask all of you in submitting written comments to kind of go beyond that. It's very helpful, for example, you brought this device and gave specifics about individual instances where this is a problem for you.

But of course, and we are certainly considering the options, all of our options including severing the record-keeping element of the rule, but it's helpful in addressing that issue and making these sorts of determinations, to know what we would be severing it for. What are the alternatives? What would you have us do in a final rule? Because as I'm sure you're aware, and as David mentioned earlier, we have the Government Paperwork Elimination Act with a mandate that we can finish this process up by 2003.

And it's helpful in making that decision to know what sort of alternative record-keeping criteria you would envision that's not sort of triggering concerns that you have with CROMERRR. If it's issues of redefining what a record is, those are helpful comments. If it's stripping off particular criteria from those that are enumerated in the rule, that's helpful. Bearing in mind, of course, as I'm sure you're aware, the agency has another clientele in addition to those in the regulated community. Those in our enforcement

community also are going to have competing concerns.

And to the extent that you can anticipate those sort of concerns and address them in solutions that you recommend to the agency, that would be extremely helpful. Because the task that we all have is to reconcile these competing interests. And to the extent that you've helped us do that, it's more likely that we will succeed.

David Keyes: Again, OECD allows the flexibility of your definition of raw data and I think that's a key element in trying to be able to meet what you're looking for. And as I said, if you have that allowance for definition of raw data, then in the case where we have these small types of Hobo instruments or other things, as long as we can define what the raw data is, we would be able to work with that.

Jim McClain: Good morning. My name is Jim McClain; I'm from Abbott Laboratories. And as a FDA regulated community or entity, I'd like to make a couple of comments regarding this rule. First of all, we support EPA in an effort here to try to do something relative to appropriate electronic reporting and record-keeping. We think that's an appropriate undertaking. But having had some experience with the FDA Part 11 rules, we're very concerned with some of the issues that have been pointed out this morning which deal with

interpretation of the definition of data and the extent of the rule.

We're very concerned with just how far upstream these requirements may go, as has been pointed out. At least one of the interpretations here is that keeping any form of electronic record takes it out of being a voluntary rule to being a mandatory rule. And if you are going to parallel FDA Part 11 rules, that implies that there are going to be requirements for validation and documentation of all of those systems.

And the cost of that validation and documentation of those systems can be enormous. And if that is not taken into consideration as part of the cost of this, then you've missed a major portion of the cost to the industries. It's already been mentioned that there's some concern that the cost estimates were significantly underestimated. I don't know what went into this particular cost that's listed in the rule here. I haven't done any study about it, but we would be concerned that that number does not include some of these additional costs and expenses to a company to follow up on the validation and the documentation requirements for such systems.

We have found that FDA Part 11 rules have required, in

some cases, significant numbers of additional head count to follow up on their requirements. And that is an expense to the company. So I think the EPA has to think very carefully about just how far upstream do they really intend for these requirements to go. What is the benefit to the entire community for those expenses to the companies? And what are the real expenses associated with that? Just a word of caution.

Subpart D - Electronic Reporting and Record-keeping under EPA-Approved State Programs:

David Schwarz: The last part of the rule is on electronic reporting and record-keeping under EPA-approved state programs. The general question is, why address state programs. The answer is that under most environmental statutes, the relationship between EPA and states that implement EPA programs is governed by regulations under which EPA approves particular aspects of state programs.

And our understanding, based on legal analysis, is that in many cases, where a state introduces electronic reporting or electronic record-keeping, under its programs that EPA authorizes, that this constitutes a change that needs EPA

approval.

I guess that's a long-winded way of saying that we've written CROMERRR against the background where there is some oversight of state programs provided for under various program specific regulations. CROMERRR doesn't create that oversight relationship but since it exists, CROMERRR attempts to provide some criteria in the cases where the oversight involves approving electronic reporting and record-keeping programs.

And what the rule does, what CROMERRR does, is to offer criteria for these approvals. And we have a couple of goals. One is to try to foster consistent electronic government across state lines. We think that's good government, international interest. And we'd also like to offer to the states, who are our partners in implementing these programs, a consistent set of standards and perhaps the possibility of a streamlined approval process across their programs that uses the same criteria and process in each case. So it's sort of, again, an attempt at consistency, uniformity and efficiency. And that's really the goal of these electronic reporting criteria.

I guess I should probably say as a background to the criteria themselves that, as with EPA's standards for electronic reporting and record-keeping under our programs,

one of the goals, or one of the things we always have to keep in mind is the fact that the documents that states take as electronic reports in their systems have to be able to play whatever role their paper counterparts play in all legal context, including in some cases, enforcement proceedings. So the criteria for their electronic reporting systems is meant to ensure that what they get meets these same general goals that have informed our own approach.

I guess the other thing is that the criteria that we lay out are meant to be technology neutral. They also are criteria that we've attempted to adhere to ourselves as we developed our own central exchange system. So that's a bit of background.

Anyway, the topics covered are system security, the method of electronic signature, the submitter registration process, the electronic signature certification scenario, what we call a transaction record and a system of archives. Again, I should stress these are criteria that apply to states, or in some cases local government agencies. These are not criteria that are meant to apply to regulated companies submitting electronic reports. So just view them in that light.

Well, let's go through some of them. In the case of general system security, nothing here is too unusual or

remarkable. It's basically good system management. So I don't know what I'm going to dwell on those here.

Let's move on to electronic signature method. This is perhaps a little bit more interesting. Clearly the signature method has to provide a way of uniquely identifying the individual signer. Otherwise it doesn't sort of (inaudible) signature. The signature method has to provide for binding of the signature to the document signed. That is, once the signature is signed, it can't be possible to change the document that was signed without it being detectable.

We have that on paper because we can see, well we have it to some extent on paper although it's not perfect. But you can sometimes see when things have been erased and inked over. If you can sign an electronic document and then it can be changed afterwards by someone else, then the signature really doesn't mean anything. So that's very important to us.

Then, there have to be protections against unauthorized use, protections against the signature itself being excised or changed once it's affixed. And the method has to link or support some of the other criteria, the registration process and what we call the signature certification scenario. So let's move on to those then.

In the case of the registration process, and this is

something that goes back to doing what we talked about in the context of CDX, the process has to provide evidence that the prospective identity. It has to create a unique connection between the signature device and the submitter so that it is his or her signature. We think that there needs to be an explicit electronic signature agreement, specifying the force of electronic signature and the submitter's obligations to maintain the electronic signature device.

I should probably say parenthetically that the reason why we require this is that in the context of our culture, where we are at the beginning of the 21st century, electronic signatures are still new and people don't always understand them the same way and we can't be sure. I think we're all very used to wet ink on paper signatures, but in the case of the electronic environment, we feel that we really need to make explicit what this thing is, what it means, how you have to handle it. And that requirement may be less and less important as we go along. But we think it's important right now.

Finally, it has to be possible to de-authorize a signature. I mean, if there are problems, then you have to be able to do something about it. So that's the registration process.

David Schwarz: ...And it should be possible in retrospect to be reasonably certain what the intention was of the signer. And so if the scenario doesn't somehow create an artifact that enables you to tell retrospectively what was going on, then there's a problem.

So to begin with, the system has to make sure that the signer knows what he or she is doing, that they know what they're certified to. And the way we put it is that there at least has to be an opportunity to review what's being signed in a human readable form. We're not going to stand over your shoulder and make sure that you read it, but you at least, just as when you sign several discharge monitoring reports, no one stands over you and makes sure that you look at every value. But at least we need to know that you could have if you wanted to, that it was there in human readable form. So that's one aspect of the scenario.

We want to make sure that acknowledgment is provided for, and that's partly a protection because in the electronic environment, at least right now, it's always conceivable that one's electronic signature device, whether it's a PIN or a code or a digital signature, might have been compromised. Someone else might have gotten access to it. And so we want to make sure that you have a way of knowing after the fact

that a report has been submitted with your name, and that's what the acknowledgment provides for.

And then finally, going back to the idea of this artifact, if you will, this is meant to be the counterpart of the original document. We're not going to have a piece of paper, but what we do want to have is a file, which is the record of the transaction. It includes sufficient contextual information, so that we know what the submission means. It includes your signature. And it's something that we think we may not have expressed quite correctly. But the idea is that we think that the receiving agency ought to sign over that, to as it were, lock the file so that it cannot be tampered with down the road, so that we can be absolutely sure that this is the thing that you submitted.

And of course, we want to make sure that this can be made available to the submitter for review, or re-review, in case there is some problem or discrepancy. We want to make sure that people have a chance to raise their hand and say look, that's not what I sent or it's not what I intended to send. So that's the signature certification scenario.

The transaction record, basically is just primarily a copy of the record, as much routing and transmission information as is practical to capture, and to the extent that

we can have it, the date and time of the transaction. So that's sort of the transaction record. That's what we expect the system, whether it's our system or state system, to archive. And again, this is an archiving and record-keeping requirement on us and the state. Thanks.

We want the system to maintain the transaction records for as long as we need them, and that might be a very long time. We may find, we may find that our states have some of the same electronic archiving issues that you're struggling with, in thinking about our records. But somehow that requirement has to be satisfied directly or be a migration to some other medium. Records need to be preserved without modification and made readily available when we need them.

So those, in broad overview, are the various categories of kinds of criteria that we think any government run electronic report receiving system needs to satisfy if it's going to meet our needs for legally filed documents. That's the criteria against which we will look at the state systems.

Those are our contact email addresses and phone numbers and I encourage you to keep in touch if you have any additional thoughts to share with us, please feel free to call or send us an email.

Male Participant: Yes, David, was there any difference as we

look at these slides, this is what the states have to abide by, maintain, whatever. Is there any real difference between what they have to do and what we have to do, as a company and reporting community?

And the second part of the question I guess would be is, are these requirements for them to transfer, CDX whatever you want to call it, to transfer the data from their state databases to the EPA? Or is this designed, are all of these criteria are designed, on how to manage data that companies send to the states?

David Schwarz: Let me take those in order. These are not meant to be the same as requirements that companies have to satisfy when they submit reports. What exactly a company has to do will depend on the particular system they report to, but for example, and I know this doesn't cover all the cases, but if you're submitting a relatively short report to EPA electronically, one way to do it is simply to take your browser, go online, log in to your mailbox on CDX, fill out the form, apply your electronic signature, and submit. You don't have to worry about all this stuff. If you're submitting things in some kind of a batch file transfer mode, as opposed to filing out a form online, again, that will depend on the supporting software.

But one possible scenario would be that we would provide you with a sort of signature module, and I'll give you a possible example. Suppose you want to send us a file in an XML format. Well, XML formats are readable if you use the appropriate style sheet. You can read them, you can review them on your browser. We might give you a style sheet or an XML conversion that would allow you to do that, and just ask you to sign in that framework. And you would sign the file and send it off to us.

I think there are a number of possible scenarios, depending on how we implement our system, how a state implements their system. But in none of them would you have to worry about most of the things that we've been talking about here. These are things that I hope very much will be transparent to the submitter. You know, there are things that you have to take account of if you're constructing one of these systems to receive reports, but once you do that, you shouldn't have to worry about it as a submitter.

I guess your second question is, will the states have to worry about these when they transfer their data to us. And the answer there is no, as well. I mean it's the same thing. When they're playing the role as a submitter, they just need to worry about whatever's required to get the file to CDX and

we're trying to make CDX as user client friendly as possible. So again, they don't have to worry about the bells and whistles behind the scenes that make it work. And that's not something that user clients should have to worry about.

Male Participant: Let me ask another question. We have, we had two public hearings; this is the second one, Washington, DC, being the first one. We have one state representative from EPA state here from Illinois. How many states were represented, knew enough about the rule, or were concerned enough about the rule to participate in the public hearing in DC?

David Schwarz: Well, rather than answer that directly, let me answer it by saying that in addition to the public meetings, we had a state meeting convened by the National Governors' Association. We also, and I believe something like ten to fifteen states participated, but leading up to the writing of the proposal, we had an NGA sponsored two-year process in which 35 states participated that led in many ways to the development of CROMERRR as you see it. And that's an ongoing process.

There are a couple of state organizations through which we consult with states, and we're very glad to have Bruce Carlson here from Illinois, but we have other venues through

which we consult with the states.

Craig Black: Craig Black, I'm O2 Blue. Is the EPA publishing an XML standard for states to abide by in submitting data electronically?

Joe Retzer: Yes, we actually, what we're doing is there's EPA is forming a network with states called the National Environmental Information Network for exchanging data with states. We've been working with them about how we're going to administer this network and right now the discussions are leading toward a joint state/EPA group to do that. And as we go forward with each individual report or set of reports to implement, we are coming up with an XML standard, and a registry to put those standards into, so that they'll be available to any state or really to any person who would be interested in them.

Craig Black: Are you going to invite other stakeholders to participate in the development of that standard?

Joe Retzer: The way that we have been doing this so far, we just have done a couple; one for the error omissions (phonetic) inventory as one. We're working on another one for permit compliance data and water for the PCS system. We haven't been, because it's really just a state EPA communication, we haven't been inviting external folks to

this.

Craig Black: Right. Other companies have to report to states, though, and so what you decide actually does affect the constituency of the state agencies.

Joe Retzer: Okay, I mean the idea is that states may internally have any kind of database that they may be storing that data in and it's a wide variety of different approaches. The idea is, they need to be able to get from whatever their state system is into this XML format.

Craig Black: Thank you.

Dick Lowery: You do have copies of mine; I have some extras if anybody else is interested.

Good afternoon, I'm Dick Lowery, L-O-W-E-R-Y, a senior environmental coordinator and an IT project manager at BP in Lisle, IL it's a suburb out here in the west suburbs. I'm pleased to have this opportunity to offer our comments on EPA's proposed CROMERRR rule.

BP is a global petroleum and petrol chemical company with many facilities in the United States that are subject to EPA reporting and record-keeping requirements. In general, BP supports EPA's effort towards electronic environmental reporting, electronic signatures and electronic record-keeping. Your intentions mesh well with our goal to be a

progressive company whose operations are open and accessible to our communities and customers. But as proposed, CROMERRR won't work for three main reasons.

First, it's not a voluntary program as EPA says it is. And this means that there are large numbers of businesses who don't yet know they're affected. Second, CROMERRR is far too prescriptive. And third, it's going to be expensive, and for what result. Therefore, we suggest as a minimum that EPA should sever the record-keeping provisions from the rest of the proposal, withdraw them for further analysis. Also, EPA should provide a 60-day extension on the comment period for the reporting and signature sections. Let me explain why.

Is CROMERRR really voluntary? We think not. EPA proposes CROMERRR to apply to any computer managed record that supports or documents any EPA compliance requirement either to support data in a required report or to document data use to find the decision that you don't have to report. So virtually the entire reporting community is involved. Regulated community is involved.

But electronic records are already almost everywhere in the business. So meeting EPA's applicability requirement would mean either reverting to paper records ... and we discussed that, which I don't think you can really do ... or

modifying existing electronic record-keeping systems. In practice, therefore, CROMERRR would be mandatory for some 8.2 million facilities that are regulated under 40 CFR.

The burden would be greatest for the 1.7 million facilities that are obligated and actually submit reports under 40 CFR. So there's a large community out there that are regulated in reporting that CROMERRR would affect.

Most of these affected facilities have no idea that they would be prohibited from using a computer to keep any EPA records. Most states, and this may be wrong because I don't have your information there, so thanks for sharing it David, but most states we thought did not realize the impact of EPA making on their current electronic reporting null and void. Now maybe Illinois recognizes that, that according to the rule as CROMERRR set out, until EPA decides to say yes you can start electronic reporting, that all of the electronic reporting systems they have would be null and void. So we think it's necessary for EPA to extend the comment period by 60 days. And conduct an intensive outreach effort to allow the affected reporting community time to realize CROMERRR is not voluntary and that they are affected in very significant ways.

Why do we think CROMERRR is overly prescriptive? In many

places, CROMERRR specifies new ways to do record-keeping, reporting and signatures, when suitable methods already exist. For example, why not use the relatively simple current e-signature legislation? Public law 106-229, rather than generating a new nine step criteria for CROMERRR. And again, my boss is not going to carry his desktop with him in order to do signatures.

And will it be expensive? BP thinks so. We are a fairly sophisticated user of electronics and some of our sites have hundreds of computer applications dealing with environmental record-keeping and reporting. And we have thousands of sites. If we assume we have to look at each of our applications in a fashion similar to what we had to undertake for Y2K, and I think we're calling that the very bottom low level floor of cost, it would only cost our company $150 million to try to implement the record-keeping portion of CROMERRR. And again, we think that is the very bottom floor.

Even EPA thinks it's expensive. The conservative estimate, using EPA's own $40,000 per site estimate, plus $17,000 maintenance every year. If you take those two numbers, what is that, $57,000 of the first year, the reporting facilities ... 1.7 million ... they would only have to come up with $68 billion this first year. And you also

have the other facilities, the small facilities who don't have to report, but they do need to manage their data and if they have any computers at all, it will apply to CROMERRR and they will have to have all of this additional auditrail, and using EPA's numbers of $57,000 for the first year, that would only come to an additional 260 billion dollars. So we're already up over $300 billion of the first year for something that EPA wanted to promote as a money-maker and able to go on without doing any cost-benefit analysis.

Amazingly, EPA seems not to have supported the need for such huge expenditures. For there is little or nothing in the public record addressing the impact of the record-keeping provisions on regulated facilities. What excessive electronic fraud ... this is getting back to mike on the legal side ... what is the overlying pressing requirement that EPA feels that there is so much electronic fraud out in industry that we have no ethics and no morals, that they must require this detail?

And I'm going to come back and say, maybe we're wrong Mike, but we don't have this amount of detail of documenting date time stamping, user stamping every piece of paper that we've got. I would like to say that you're, pick up on what you've got and say that the electronic data, boy if you could make that the same as the paper data, we wouldn't have this,

you know, we'd be on the same page.

Thus, regretfully, BP cannot support CROMERRR as proposed by EPA. We urge the EPA to extend the comment period for the reporting and signature sections and conduct outreach to the many facilities that may not know that they're affected. And we urge EPA to sever the record-keeping sections of the rule and withdraw it for further work.

I would like to take an opportunity, less than five minutes, to give a couple of concrete numbers on the record-keeping side if you would. Just for EPA to get a sample or idea of how large of a problem this is, and what the cost is. We're in a .... everybody out here knows that we're in a computer age. I mean we've been in it for decades. Everything you've got is on a computer someplace. According to the rule here, I believe that you're audix messages, your electronic telephone messages that gets managed through a telephone system with a computer, you're probably going to have to archive all your audio messages for the next five years. Let's see.

Electronic signatures do need to be simple. Again, I don't think it can be tied to ... it's got to go from that one particular computer. There's some way to make a little simpler; you may not like it for the records, but put a pin

number or something. If you can set stuff up and you don't have to go down and have two IDs and all that stuff to get it, and my boss does not have to give out his credit card number to somebody, you know. We would be happy with that. For him to come in, sign the signature, you know, it doesn't require that he have that now. And if that is a big overriding factor for legality purposes, we're more than willing to send you a one sheet of paper with a signature on it saying we sent you the electronic data.

On your stuff, if you want to turn to your last three pages there where I really talk about numbers and cost, we have several large programs. We'll spend two million dollars and fifteen man-years of effort to put together a program so our refineries can try to calculate TRI to the best we can. Toxic release inventory. And so with that purpose, we spent two million dollars and it will cost a quarter of a million dollars just to be able to time date stamp user stamp all the information that's in there. So that comes out to be about 10 or 15 percent.

My comment is if you're looking for some sort of a ball park number, on what it's going to cost you to modify simple programs that don't cost very much or large programs that are quite complex, that do cost a lot, use a 15% ... 10, 15

percent of development costs. That's probably what it's going to cost you to repair this if you don't have your date time user stamping.

We've got some large facilities. One of our large facilities has 324 separate applications. And Dave, I don't know if we've gone into the lab and got every single software that's on all of the instruments, so that's probably no included in there. At our local refinery here in Whiting (phonetic) we collect processed data. We did an average piece of data, an average temperature, and average snapshot for the day. We collect 61,000 pieces of data, put it into this one system and that's the daily average. And if you go down and see that the daily average, but if it came from just one minute averages, I'm sure there's some out there that have every six seconds they're taking stuff, but if it's just one minute averages, that only increases that database by 1400, a factor of 1400. So over a five year period all we have to do is store 150 billion pieces of data; 150 billion records have to be tagged, stored and easily retrievable.

Right now, if you have a process engineer that wants that piece of data from yesterday, how easily retrievable is it for you to give him that when he needs it? But say for five years, the EPA is requesting that this data be easily

retrievable.

Okay, in addition to those kinds of costs, in addition to the initial cost, you also have to maintain these systems. You also have to when you do make a change, to put the simple stuff in, you have to hope that they didn't screw up the rest of the program and that it doesn't screw up your process, if these computer programs are used for any process control.

Your email. Are you going to maintain ... how much email do you keep? Do you keep everything? Do you purge 80% of it? Do you have records much longer than a year old? You're now going to keep all 100% for five years. Can you imagine the servers your company's going to buy to maintain all of the electronic data that you're going to have to keep for that? What's going to happen to your performance? What's going to happen to your performance on these applications? It's going to go right down the toilet.

So anyway, I guess where I'm coming from is, it has great, great impact. And if I understood what the initial message was, is EPA is managing three percent of it. The states have 80%. And if, and they're really going after the paper pieces, not the magnetic media piece. And my comment is, is well let's go to magnetic media as a first step. It's not quite electronic but damn close to it.

Let's go to the electronic step and have people turn in their data on CD ROMs or diskettes, and you're almost there. All you have to do is instead of me pushing the button to upload the data is to have a clerk that you have that can push the button when the diskette is in the computer and upload the data. You're getting, I was going to say 80%, but you're probably getting 95% of the bang for almost no cost.

And if you want to stay with paper, charge the ma and pa cleaners out there $25, $50 if they want to submit in paper, or give them the discount if they submit on diskette. If you want that electronic transfer, build something in your rules to manage that electronic transfer. Don't go all the way back to when my data's created when I took a temperature on a reactor, and say we're going to hold you more responsible for that than we do right now when it's on paper.

It is tremendous. And so I'm anticipating my company, if we had to abide by this thing, we're going to spend hundreds of millions of dollars to do this and virtually no benefit. And I don't think my company's committing (inaudible) they're not committing fraud, they're not being electronic data fraudulent intentionally at all. And if you got somebody out there, go after them. Put these rules on them and let them spend the $100 million so you can track them.

You're welcome to come to our facilities and inspect as you have in the past, and we will give you the data that supports what we've done. Thank you.

Joe Retzer: I guess I have just one thing and that is, you're asking here sort of why didn't we just use the e-sign legislation. Well, unfortunately the e-sign legislation ... I say unfortunately, because that would have been very simple if we could have done that. But unfortunately company to government reporting is specifically excluded from that legislation. That's why there's GPEA and a set of guidance related to Government Paperwork Elimination Act provided by the Office of Management and Budget and if you read through that guidance, it looks like there's a wider range of considerations that agencies need to take into account for the government company relationship as opposed to commercial transactions.

Dick Lowery: Joe, if you can't use that law, maybe you can use that law as your straw man and put a new name on it, and maybe you need to change a few words, maybe you need to add something. I don't know if you need to add seven more steps to the two that are there, but make it simple if you can. As you pointed out front, if you make it simple, they're going to use it. If you build a Cadillac and it's difficult to get

that garage door open, nobody's going to go in and use it.

We support you on what you're doing; we just don't want to be prescriptive. Let us be able to transfer the data to you and if we build it, if you have an interface that won't corrupt that data, we're happy. I can put a 34 cent stamp on that CD ROM and get it to you guys great. But if I've got to go out and spend hundreds of millions of dollars in order to push the button and get it to you faster, it's not worth it to me. We do support you in your efforts.

Michael LeDesma: I should probably add something as well in response to your comments, principally because I mean, there's certainly a great deal of concern with the record-keeping provisions and I don't want people to go away with a mistaken impression of what the rule does. You made a comment that this rule would potentially invalidate ongoing state electronic reporting. And I wanted to be clear that this rule, in certainly intent and I believe the wording as well, has no impact on ongoing electronic reporting to states.

We know it's going on. We have devaluated it and we think it would be unfair to the states, in particular, and invalidate the reporting that's going on in those instances. Of course, as David explained, there are record-keeping provisions that govern state programs that will eventually

kick in under the existing regulations where there is usually a phase in period. They get one year to revise, or two years, if they need to go to their state legislatures for revisions of state law.

That's generally the case. So I mean to be clear, we're not impacting that at all in this. We're not blessing it, we're not saying it's invalid. We're just not speaking to it.

Dick Lowery: I just wish you'd do the same on my electronic data that I have that I've been using for years and years and years to support paper or magnetic media. I sure would appreciate if you took the same approach with me and said, you know I've got it, you know I'm using it, it was good enough yesterday. I sure hope it's good enough tomorrow. Thank you.

General Discussion

Joe Retzer: ... a version of what we thought, while the FDA rules are pretty prescriptive in terms of the technologies, what we came up with was a version of that that's based on criteria or performance criteria. That's our approach, that's basically parallel. And we had some public meetings with industry appearing and what folks urged us to do was to be consistent with that approach. So people did have a chance to

appear at those public meetings and we did hear a lot of comments. And that was last year, last fall around this time. Maybe it was even earlier.

David Schwarz: (inaudible) we haven't heard any comments that make us think we can't go forward at least on the reporting side. And you know on the record-keeping side, I guess we'll just have to put our thinking caps on. We do want to get all the comments. We know the kinds of issues that have come up in this room today are issues that have come up in other places and we have to take them seriously. And what exactly we do, I think, will depend on how easily we think we can resolve the questions.

Deanna Heffron: I don't really have any comments, I just have some questions. Under the additional options of the proposed rule of the record-keeping, on page 46170, one of the bits that was included was that EPA may determine that additional provisions are required for electronic records. And then on the following page, it goes, outlines some of the items. I'm guessing they're in the current FDA regulations. I'm not familiar with the FDA requirements for electronic record-keeping.

David Schwarz: Yes, I think these were pulled from the FDA regulations.

Deanna Heffron: What is the likelihood that these additional requirements for the record-keeping, electronic record-keeping will be put into place in the final rule.

Joe Retzer: What is the likelihood? Not high.

David Schwarz: I'll give you my basic understanding of the difference between our and FDA's approach. Theirs is a lot more detailed than ours. The other thing is, they have a lot of focus on things like verifying and certifying (inaudible) while we're not putting anything prescriptive in here that says how company must verify or do that. For example, I think FDA's interested in certifying particular (inaudible) and we're not interested (inaudible).

Joe Retzer: Just one other follow up comment. Although I don't think we're going to change the CROMERRR criteria in the direction of greater stringency, we may make them more specific in the sense of narrowing the scope of certain requirements or identifying more specifically where they apply. It may turn out that, beyond that, that CROMERRR may address sort of baseline requirements for electronic record-keeping.

And then in the case of individual programs where for programmatic reasons, the feeling is that they need more stringency, that they set up on a program-by-program basis,

these would be regulatory activities of other parts of the agency. So that would always be a possibility.

Deanna Heffron: So then at this point in time, there's no intention for CROMERRR to include any of the current FDA items with the written policies governing education and training of personnel and certification of persons who develop, maintain or use electronic records signatures systems and verifying that they have all that education and establishing training programs and retraining or anything like that?

David Schwarz: I think that's unlikely to be in the regulatory text. It's conceivable. There was a woman from Monsanto who made a couple of suggestions that if we were going to base our approach generally on FDA that it would be good to cross reference our more generic requirements with specific requirements in FDA. If we end up continuing with that approach, I could imagine in the preamble or in a guidance document referring to some of these things as ways among others to meet some of our general criteria. But I think it's unlikely that it would get to that level of prescriptive specificity in the regulatory language itself.

Deanna Heffron: So at this point in time are you expecting comments from the public regarding this proposed additional record-keeping or electronic record requirements?

David Schwarz: You know, we would certainly welcome those comments, I mean if it turns out that there is a community out there, or a constituency that really feels strongly one way or the other, in favor or opposed, that would be useful information. I'm not hearing a groundswell of support for including these, but we haven't gotten all the mail yet, so.

Joe Retzer: Yes, we've really done, probably just like anything else, the vast majority of the comments are going to come in the last week, so we don't really know.

Lynn Calvin: I'm Lynn Calvin, I'm actually an EPA person from a region. Isn't that education and training language, David, from the ISO 9000 language?

David Schwarz: It may be. Some of it. I'm sure that we pulled things from a variety of sources, so it's possible that that's where it's from.

Lynn Calvin: Okay, I'll pursue that later. But that phrase sounded, if it isn't ISO 9000, there's stuff real like it in ISO 9000.

David Schwarz: Let me ask you a question. If it is in ISO 9000, does that have any implications we should be aware of?

Lynn Calvin: Well, if entities are ISO 9000 certified, they have some baseline records management in place. And basically they have policies and procedures for records management,

paper or electronic and some mechanism for monitoring that there is some compliance and education in those. That's part of what ISO 9000 does. It's at the 10,000 foot level, but it indicates that there is records management. And that's, but the CROMERRR language about education and training sounds like ISO 9000. I'm not sure.

John Bernstein: John Bernstein, I'm from EPA region 5. If the language is not from ISO 9000, it could very well be ISO 49, which is a records management standard that ISO has developed separate from 14000 and 9000.

David Schwarz: If some of these things are specified in ISO standards, are there EPA programs, whether through regulation or guidance, that refer to these ISO standards. Or is this just something that's out there that some people try to comply with?

John Bernstein: I would say it's the latter. Some people try and comply with them. On the other hand, it's my own feeling that businesses that do business internationally are trying to comply with ISO 9000, or for that matter 14000. I don't know how many businesses out there are complying. I haven't heard anything at least in my contact list with EPA.

David Schwarz: Okay, thanks.

David Keyes: This is David Keyes from Dow Agra Sciences. I

had talked to David a little earlier, but I wanted to ask this as officially: if you would be amenable to consider the 60-day extension for comments. Dick Lowery brought that up in his piece but I wanted to just make sure to ask that question separately.

Michael LeDesma: I guess the answer is, we can consider it. I don't know what the real benefit would be. But if we decide to do that, we would publish a notice in the Federal Register that says we were going to do that.

Joe Retzer: I'm sorry, what's your special concern for why we need a longer comment period?

David Keyes: Just due to the far reaching scope and the amount of people that are involved with this. It's taking time to get everybody to get their comments in and be aware of this.

Deanna Heffron: I just wanted to make one comment. With some of the questions I realize that this proposed rule is just supposed to be a framework and allow for quite a bit of flexibility. (inaudible)

End of Informal Hearing